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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/019,676	04/08/2002	Sam Fong Yau Li	2577-118	7819
6449	7590	11/01/2005	EXAMINER	
ROTHWELL, FIGG, ERNST & MANBECK, P.C. 1425 K STREET, N.W. SUITE 800 WASHINGTON, DC 20005			LUCAS, ZACHARIAH	
			ART UNIT	PAPER NUMBER
			1648	

DATE MAILED: 11/01/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/019,676

Applicant(s)

LI ET AL.

Examiner

Zachariah Lucas

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 23 September 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 73-91, 94-100 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 73-91 and 94-100 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### DETAILED ACTION

1. Claims 73-91 and 94-100 are pending and under consideration.
2. In the prior action, mailed on March 23, 2005, claims 73-100 were pending, with claims 73-91 and 94-100 under consideration and rejected, and claims 92 and 93 withdrawn as to non-elected inventions. In the Applicant's Response of September 23, 2005, the Applicant cancelled claims 92 and 93, and amended claims 73, 79, and 95.

#### *Claim Rejections - 35 USC § 112*

3. **(Prior Rejection- Withdrawn)** Claims 73-91 and 94-102 were rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. Claims 101 and 102 have been cancelled. In view of the amendment of claims 73 and 95 such that the claims now require the presence of an electrode, the rejection is withdrawn.

#### *Claim Rejections - 35 USC § 103*

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. **(Prior Rejection- Maintained)** Claims 73, 74, 76, 78-81, 83, 84, 90, 91, 95, 97, and 99-100 were rejected under 35 U.S.C. 103(a) as being unpatentable over the teachings of Bastiaans

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et al., (U.S. Patent 4,735,906, of record in the April 2002 IDS), in view of Larue (U.S. Patent 5,705,399) and Thorns (U.S. Patent 5,510,241). U.S. Patent 5,306,644 was cited in the Advisory action as additional evidence that it would have been obvious to those in the art to use the device suggested by the other references in immunological assays in veterinary applications. For the sake of clarity, the recitation of the rejection is hereby restated to be further in view of the teachings of the '644 patent. The Applicant traverses this rejection based on the a new limitation in the claims that the second contacting "occurs without the need for a prior washing step following the negative test," and arguments asserting that the re-use of the device after a negative sample without washing is not disclosed by the prior art.

The traversal is not found persuasive for two reasons. First, the claims do not exclude the inclusion of a washing step in the claimed method. Thus, the claims read on methods that may include a washing step, even though such a step would not be necessary for conducting the new assay.

Second, even if the claims were to exclude such a washing step, the Applicant has presented no more than an unsupported assertion that reuse of the device without washing after testing a negative sample would be non-obvious. This argument is not found persuasive because the art teaches the reusability of the device, but discloses the need for washing the device (or otherwise removing bound materials) only after a positive sample. It would have been apparent to those of ordinary skill in the art that, after a negative sample, none of target analytes would be bound to the Pz crystals. Thus, it would have been obvious to those of ordinary skill in the art to reuse the device without washing, although washing may be a preferred embodiment for scientific and statistical purposes (e.g. to ensure a clear binding surface for later tests).

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Nonetheless, based on the teachings in the art, and based on reasoning from the knowledge available in the art, it would appear that it would be obvious to those of ordinary skill in the art to reuse the device used in the claimed methods (and in the prior art) without additional washing steps after running an assay with negative results.

It is noted that the Applicant asserted that a declaration under 37 CFR 1.132 in support of their position was to be forthcoming. However, this declaration cannot be considered in the present action as no such declaration has been entered into the application as of one month from the submission of the Response (the time of completion of the present action). It is noted that Applicant is no longer entitled to the consideration of Supplemental replies under 37 CFR 1.111 unless the supplemental reply is submitted during a period during which the Office is suspended from action under 37 CFR 1.103 (a) or (c).

The rejection is therefore maintained.

6. **(Prior Rejection- Maintained)** Claims 73-76, 78-81, 83, 84, 90, 91, 95-97, 99 and 100 were rejected under 35 U.S.C. 103(a) as being unpatentable over the teachings of Bastiaans et al., (U.S. Patent 4,735,906, of record in the April 2002 IDS), in view of Larue (U.S. Patent 5,705,399) and Rajashekara et al. (WO 98/03656). The Applicant traverses the rejection for the same reasons as described above. For the reasons above, the traversal is not found persuasive and the rejection is maintained over the new claims.

7. **(Prior Rejection- Maintained)** Claims 77, and 85-89 were rejected under 35 U.S.C. 103(a) as being unpatentable over Bastiaans in view of Larue and further in view of either

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Thorns or Rajashekara, as these references were applied against the previous versions of the above claims, and of Willner et al. (WO 98/40739, Willner I- of record in the April 2002 IDS).

The Applicant traverses the rejection for the same reasons as described above. For the reasons above, the traversal is not found persuasive and the rejection is maintained over the new claims.

8. **(Prior Rejection- Maintained)** Claim 82 was rejected under 35 U.S.C. 103(a) as being unpatentable over Bastiaans in view of Larue and further in view of either Thorns or Rajashekara as applied to the previous pending versions of the above claims, and further in view of Willner et al. (WO 97/04314, Willner II- of record in the April 2002 IDS). The Applicant traverses the rejection for the same reasons as described above. For the reasons above, the traversal is not found persuasive and the rejection is maintained over the new claim.

9. **(Prior Rejection- Maintained)** Claims 94 and 98 were rejected under 35 U.S.C. 103(a) as being unpatentable over Bastiaans in view of Larue and further in view of either Thorns or Rajashekara as applied to the previous pending versions of the above claims, and further in view of Masten et al., J Bacteriol 175: 5359-65 and in view of Protein Accession CAA78777. The Applicant traverses the rejection for the same reasons as described above. For the reasons above, the traversal is not found persuasive and the rejection is maintained over the new claim.

### ***Conclusion***

10. No claims are allowed.

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11. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachariah Lucas whose telephone number is 571-272-0905. The examiner can normally be reached on Monday-Friday, 8 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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Z. Lucas  
Patent Examiner

  
JAMES HOUSEL 10/28/05  
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